



GUIDANCE DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (9 CFR 121 and 7 CFR 331).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities in complying with this legal obligation.

A registered entity is required by law (42 CFR 73.17, 9 CFR 121 and 7 CFR 331) to contact CDC or APHIS immediately upon discovery of a theft or a release of a select agent and toxin not authorized under a federal act. The agency that the Responsible Official (RO) should contact is determined by the type of select agent or toxin involved in the incident. For HHS agents, the Responsible Official (RO) must contact CDC (telephone: 404-498-2255; facsimile: 404-498-2265). For HHS/USDA overlap agents, the RO must contact both APHIS and CDC at the numbers listed (for USDA after hours call 1-866-994-5678). For USDA agents, the RO must contact APHIS (telephone: 301-734-5960, or facsimile: 301-734-3652). A listing of HHS select agents and toxins is available at <http://www.cdc.gov/od/sap>. A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The list of plant agents and toxins is available at <http://www.aphis.usda.gov/ppq/permits>.

The RO should contact the appropriate agency immediately upon discovery of loss, theft, or occurrence of release of the select agents and toxins to explain the circumstances. Notification of the proper agencies is important to assure that emergency response efforts, including medical intervention and follow-up surveillance of human or other animals potentially exposed by release of the select agents and toxins(s), are accomplished in a timely matter, if appropriate. For release of HHS select agents or toxins, the RO should also notify the local and State Health Department. For USDA agents, the State Veterinarian should be contacted; for restricted plant pathogens, the State Plant Regulatory Official should be notified. For HHS/USDA overlap agents both the State Veterinarian and State Health Departments should be notified. In the case of theft or loss, the local police and Department of Justice should be notified, as appropriate.

The theft, loss, or release of an HHS select agent or toxin must be reported immediately upon discovery to CDC by telephone (404-498-2255), facsimile (404-498-2265), or e-mail (lrstf@cdc.gov). The theft, loss, or release of a USDA select agent or toxin must be reported immediately upon discovery by calling APHIS at 1-866-994-5678 and following the instruction prompt. The theft, loss, or release of an HHS/USDA select agent or toxin must be reported immediately upon discovery to both CDC and APHIS. After the initial reporting by telephone, this form should be sent directly to CDC or APHIS, as appropriate, within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins. This requirement is not satisfied by reporting the theft or significant loss in any other manner. The entity is required to keep a copy of the notification form.

INSTRUCTIONS

RO must complete Sections 1 and 4. Section 2 should be completed for those entities for which a loss or theft has occurred. Section 3 should be completed for those entities that have a release of select agents or toxins. The RO must sign and date the form.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the CDC at (404) 498-2255 or APHIS at (301) 734-5960. This guidance document and form are also available at <http://www.cdc.gov/od/sap>, <http://www.aphis.usda.gov/vs/ncie> and <http://www.aphis.usda.gov/ppq/permits>.

WHERE TO SEND THE COMPLETED FORM

For HHS agents, return completed forms to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

For USDA agents, return completed forms to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

For HHS/USDA overlap select agents and toxins, return forms to: both CDC and APHIS at the addresses provided.

This form shall not be disclosed under the Freedom of Information Act. Under Public Law 107-188, information derived from this form is also protected from release.



REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS



Read all instructions carefully before completing the report. This report must be submitted by the Responsible Official. Answer all items completely and type or print in ink. The report must be signed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333. For HHS/USDA overlap agents submit the form to both CDC and APHIS. For USDA agents, submit document to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

SECTION 1 – TO BE COMPLETED BY RESPONSIBLE OFFICIAL				
Entity name			Entity registration number	
Entity address (NOT a post office address)		City	State	Zip Code
Responsible Official (RO)		Telephone	FAX	E-mail
Address (NOT a post office address)		City	State	Zip Code
An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: <input type="checkbox"/>				
Yes <input type="checkbox"/> No <input type="checkbox"/>				

SECTION 2 – TO BE COMPLETED ONLY FOR REPORTING LOSS OR THEFT OF SELECT AGENTS AND TOXINS		
IF LOST ON SITE OR THEFT HAS OCCURRED PROVIDE THE FOLLOWING INFORMATION		
Provide a list of all missing select agents and toxins (Complete Section 4)		
Date loss or theft noted	Date of last inventory	Name of principal investigator for laboratory with select agents and toxins
Laboratory building and room		Name and telephone number of local police department notified
Type of theft (Night break in, armed robbery, etc.)		Symbols or markings on containers (if any)
Provide a detailed summary of events (attach additional sheets if necessary):		
IF LOST OR STOLEN IN TRANSIT PROVIDE THE FOLLOWING INFORMATION		
Provide a complete list of missing select agents and toxins (Complete Section 4)		
Attach a copy of the Form EA-101 that was associated with this shipment		
Name of carrier		Airway bill number/tracking number
Provide a detailed summary of events (attach additional sheets if necessary):		
Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):		

SECTION 2 (CONTINUED) PROVIDE THE FOLLOWING INFORMATION				
	SENDER INFORMATION		RECIPIENT INFORMATION	
Name of person				
Name of entity				
CDC/APHIS registration number	CDC	APHIS	CDC	APHIS
PHS/USDA import permit number	PHS	USDA	PHS	USDA
Date shipped				
Telephone				
FAX				
CDC confirmation number from transfer form:		APHIS confirmation number from transfer form:		
Package with select agents and toxins received by requestor <input type="checkbox"/> Yes <input type="checkbox"/> No		Package with select agents and toxins was tampered with <input type="checkbox"/> Yes <input type="checkbox"/> No		
Other contents of package (e.g., coolant type):				

SECTION 3 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS		
Provide a list of all select agents and toxins released (Complete Section 4)		
Date of release	Time of release	Name of principal investigator for laboratory with select agents and toxins
Location of exposure or release (give laboratory building, room, area and surface or space involved)		
Name and telephone number of local and or state health dept. notified		Name and telephone number of emergency responders
Biosafety level of laboratory where exposure occurred		
Names of person(s) involved in exposure (attach additional sheet if necessary)		Number of animals exposed
Injuries <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, give names and occupations of individuals injured)		
Exposures <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, give names and occupations of individuals exposed)		
Medical treatment was required <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, explain)		
Provide a detailed summary of events (attach additional sheets if necessary; provide sufficient information so that the severity of the release can be understood):		
Provide a summary of actions taken: <input type="checkbox"/> Called ambulance <input type="checkbox"/> Called fire department <input type="checkbox"/> Closed laboratory doors <input type="checkbox"/> Closed building <input type="checkbox"/> Consulted MSDS or chemical database <input type="checkbox"/> Called police department (case #) <input type="checkbox"/> Other (explain):		

Provide a summary of clean up actions taken (attach additional sheets if necessary):

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SECTION 4 – TO BE COMPLETED BY ALL APPLICANTS

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED

	Select agents and toxins	Characterization of agent	Number of vials	Form (powder/liquid/slant)	Vol or wt per vial (e.g., ml, mg, ng)	Total quantity	Concentration/vial (e.g., 10 ⁸ pfu/ml)
Examples	Botulinum toxin	Neurotoxin A	50	Liquid	5 ml	250 ml	1 mg/ml
	<i>Bacillus anthracis</i>	Ames strain	25	Liquid	1 ml	25 ml	10 ⁸ /ml
	Ebola virus	Zaire	10	Liquid	1 ml	10 ml	10 ⁷ pfu/ml
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I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official (RO): _____ Typed or printed name of RO: _____

Date: _____

Public reporting burden: Public reporting burden of providing this information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).